



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,542	05/16/2001	Rajesh Manchanda	BERLX-100	9728

23599 7590 08/29/2003

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
2200 CLARENDON BLVD.  
SUITE 1400  
ARLINGTON, VA 22201

EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 08/29/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/855,542

Applicant(s)

MANCHANDA, RAJESH

Examiner

Lauren Q Wells

Art Unit

1617

--Th MAILING DATE of this communication appears n the cover sheet with th corres ndence address --

THE REPLY FILED 08 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

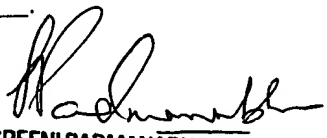
The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-4,6,8-14,16,18-22 and 32-35.Claim(s) withdrawn from consideration: 7,17 and 23-31.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
SREENI PADMANABHAN  
PRIMARY EXAMINER

8/26/03

Continuation of 5. does NOT place the application in condition for allowance because: a) the 35 USC 103 rejection in the previous Office Action is maintained for reasons of record in the Office Action mailed 8/8/03, Paper No. 9; b) Applicant's arguments toward the election/restriction requirement were addressed in the previous Office Action; c) Applicant argues that there is no motivation to combine Miller and Bannerjee, and specifically argues, "there is no suggestion from Bannerjee or from Miller to suggest that a means for adjusting tonicity in a composition for effecting bronchodilating activity would be desired or even useful in a composition, such as Miller's containing a radiopharmaceutical". This argument is not persuasive. The Examiner respectfully points out that Miller and Bannerjee are both directed toward pharmaceutical compositions for in vivo administration that are administered in a saline solution. Bannerjee teaches that adding tonicity adjusting agents to such saline solutions is desirable so that the ionic strength of the compositions can be varied and a composition can be provided for in vivo administration of an active agent that is effective and physiologically compatible with the body. Applicant argues that the two references are unrelated. This argument is not persuasive. As stated above, both are related to pharmaceutical compositions for in vivo delivery of active agents. Applicant argues, "there is no suggestion to one of ordinary skill in the art to select the particular iodide salts from Bannerjee as the tonicity adjusting agents. Since the two iodide salts are only a small portion of the tonicity adjusting agents taught by Bannerjee, one would not necessarily achieve the advantage of stabilizing the radionuclide by following the tonicity adjusting teachings of Bannerjee". This argument is not persuasive. First, the Examiner respectfully points out that the combination of the two references teaches all of the instant limitations of the independent method claim, thus, the combination of references has the same effect. Second, it is respectfully pointed out that such iodide salts are conventional tonicity agents that are added to saline solutions.

**BEST AVAILABLE COPY**